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Section 2 - Summary of Safety and Effectiveness

K003893

Manufacturer
ORATEC Interventions, Inc.
3700 Haven Court
Menlo Park, CA 94025

Contact Person
Linda Guthrie
Sr. Regulatory Affairs Specialist

Device Name
Vulcan® Ablator™ Electrosurgical Probes, Class II device (21 CFR 878.4400)
Vulcan Ligament Chisel™ Electrosurgical Probes, Class II device (21 CFR 878.4400)

Generic/Common Name
Electrosurgical cutting and coagulation device and accessories

Device Description
The Vulcan Electrosurgical Probes are single-use, monopolar, electrothermal devices intended for coagulation and cutting of soft tissues. The Vulcan Electrosurgical Probes have an insulated shaft with a thermally conductive metal tip electrode. The proximal end of the shaft is attached to a handle made of an injection molded, medical grade plastic.

Technological Characteristics
The intent of this "change being effected" 510(k) is to advise the FDA of a contraindication that is being added to the labeling of Oratec Interventions' Electrosurgical Probes (Vulcan Ablator and Vulcan Ligament Chisel). There were no actual physical changes to the devices and their indications for use remains the same.

Indications for Use
The Vulcan Ablator and Vulcan Ligament Chisel Electrosurgical Probes, in combination with the Vulcan EAS Generator, are intended for general surgical use, including orthopedic and arthroscopic applications for hemostasis of blood vessels, and in the controlled electro-coagulation of soft tissues resulting in tissue contraction (shrinkage) in joints including but not limited to the knee, shoulder, wrist, hip, etc. Arthroscopic surgery could include a variety of procedures.

Predicate Device(s)
Vulcan Electrosurgical Probes, K000691, cleared May 15, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Linda Guthrie, RAC
Senior Regulatory Affairs Specialist
ORATEC Interventions, Inc.
3700 Haven Court
Menlo Park, California 94025

Re: K003893
Trade Name: Vulcan® Ablator™ Electrosurgical Probes
Vulcan Ligament Chisel™ Electrosurgical Probes
Regulatory Class: II
Product Code: HRX, GEI
Dated: December 14, 2000
Received: December 18, 2000

Dear Ms. Guthrie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K003893

Device Name: Vulcan Electrosurgical Probes

Indications for Use: The Vulcan Electrosurgical Probes, in combination with the Vulcan EAS Generator, are intended for general surgical use, including orthropaedic and arthroscopic applications, for resection, ablation, excision of soft tissue, hemostasis of blood vessels, and in coagulating soft tissues in joints including but not limited to the knee, shoulder, wrist, hip, etc.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K003893

Prescription Use ✓
(Per 21 CFR 801.109)